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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,671	06/25/2003	James Roy Maxwell	1391/1555	4734

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WRIGLEY & DREYFUS 28455
BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,671	MAXWELL ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *42-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☒ Claim(s) *20,26 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/04;8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 41 in the reply filed on March 18, 2005 is acknowledged. The traversal is on the grounds that the examples cited by examiner are distinct from the claims, therefore the groups are not different. Applicant further argues that there is no support that the claims are independent and distinct. This is not found persuasive because as stated in the previous office action, the claims are certainly independent as claimed. In addition, the claims are distinct since other materially different products could be used to achieve the claimed method of reducing bacteria in the oral cavity, such as Listerine ©; floss or toothpaste could achieve the method of oral cleansing. As stated previously, the edible film could be made in other ways, to include using green tea extract in the film. Thus it appears self evident that the inventions of groups I – IV are all independent and distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 20, 26, and 41 are objected to because of the following informalities:

In claims 20, the term "honokoil" should be spelled correctly as "honokiol".

In claim 26, the term "cholorhexidene" should be spelled correctly as "chlorohexidene".

In claim 26, the term CPC should first be spelled out, followed by an abbreviation.

In claim 41, the term "propolyene glycol" should be spelled "propylene glycol"; and "hyroxylated" should be spelled "hydroxylated".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17 – 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 – 19 are drawn to a composition, however are rendered vague and indefinite because it is unclear if the magnolia bark extract comprises 1 – 10, 8 and 5% of the edible film, or if the edible film comprises 1 – 10, 8 or 5% of magnolia bark extract.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. (US 2002/0131990 A1) in view of Nanba (JP 57085319 A) and/or Scherl et al. (WO 01/85116 A2).

Applicant claims a pullulan free edible film composition comprising an effective amount of a film forming agent and an effective amount of an antimicrobial agent comprising magnolia bark extract. The film forming agent comprises a mixture of maltodextrin, filler and hydrocolloid; the maltodextrin comprises 5 – 60% or 20 – 40% of the film; the hydrocolloid comprises 10 – 50% or 20 – 30% of the film; the filler comprises 5 – 30% or 15 – 25% of the film. The hydrocolloid is selected from natural gums, biosynthetic gums, natural seaweeds, natural plant extrudates, natural fiber extracts, gelatin, processed starch, cellulosic materials, alginates, pectin and combinations thereof; natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthum gum; sodium alginate or calcium alginate; or a carrageenan. The filler is a food grade bulk filler selected from microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay,

talc, titanium dioxide, calcium phosphates and combinations thereof; wood; magnesium or aluminum silicates or combinations thereof; mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate or combinations thereof. The magnolia bark extract is about 1 – 10%, 8% 5% of the film; and comprises magnolol and/or honokiol. The composition further comprises an effective amount of a medicament that is that is an oral cleansing, breath freshening agent selected from pH control agents, inorganic components for tartar/caries control, breath freshening agents, anti-plaque agents, anti-gingivitis agents, saliva stimulating agents, pharmaceutical agents, nutraceutical agents, vitamins, mineral and combinations thereof. Specifically, the medicament is urea; phosphates or fluorides; zinc gluconate; chlorhexidene, CPC, triclosan or combinations thereof; a food acid selected from citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof. The composition further comprising a softening agent at about 0 – 20% or 2 – 10%; and is selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof. The composition further comprises a coloring agent; a flavoring agent at at 0.1 – 20% or 10 – 15%. The flavoring is selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties and combinations thereof; oils of citrus, peppermint, spearmint, mint, clove, wintergreen and combinations thereof; menthol, eucalyptus, thymol and combinations thereof. The composition further comprises an effective amount of emulsifier; that is selected from lecithin, (c10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof.

Barklalow teaches a pullulan free edible film comprising a film forming agent, filler, plasticizing agent (softener), medicaments and additives for treating halitosis, plaque, or gingivitis (abstract). The film forming agent is present at 10 – 90% and is selected from cellulose ether, modified starches, natural gums, polymers, hydrocolloids, seaweed, land plant extrudates and combinations thereof (0007-0008), gum arabic, guar gum, carageenan gum, ghatti, xanthum gum, locust gum and combinations thereof (0043), alginates and/or pectin (0045). The filler is present at 10 – 90% and is selected from magnesium carbonate, calcium carbonate, calcium phosphate, magnesium and calcium silicates, limestone, clay, talc, titanium dioxide, microcrystalline cellulose, cellulose polymers, wood and combinations thereof (0048). The plasticizing agent is present at about 0 – 20 or 2 – 8% and is selected from sorbitola, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof (0049-0050). The film further comprises a medicament selected from pH control agents, oral care agents, breath freshening agents, pharmaceutical agents, nutraceutical agents, saliva stimulating agents, vitamins, mineral and combinations thereof, urea, caries control agents, phosphates, fluorides, chlorohexidene, CPC, triclosan, citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof, zinc gluconate, oils of citrus, peppermint, spearmint, mint, clove, wintergreen, anise and menthol (0056-0059). Other additives include coloring agents, flavoring agents and emulsifiers (0060). The flavors are present at 0.1 – 20% or 10 – 15% (0062) and may be selected from essential oils, synthetic flavors, flavors derived from fruit (0063). Emulsifiers may include hydrogenated vegetable oils (0066) and/or lecithin (examples 1-12). The compositions further comprise maltodextrin (examples 1 – 4).

Barkalow does not teach the film wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; or wherein the claimed amounts of magnolia bark extract are present. However Barkalow does teach the medicaments may be agents for preventing dental caries, anti-plague agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolo and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the film of Barkalow, since it was a well known agent for preventing dental caries, plague and gingivitis, as evidenced by Nanba and Scherl. In addition, since such medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract in the film of Barkalow, with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

Barkalow does not teach each of the claimed ingredients in the claimed amounts. However, since such ingredients and additives are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of film forming agents in the film of Barkalow, with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

8. Claims 1 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dzija et al. (US 6656493 B2) in view of Nanba and/or Scherl.

Applicant claims a pullulan free edible film composition comprising an effective amount of a film forming agent and an effective amount of an antimicrobial agent comprising magnolia bark extract. The film forming agent comprises a mixture of maltodextrin, filler and hydrocolloid; the maltodextrin comprises 5 – 60% or 20 – 40% of the film; the hydrocolloid comprises 10 – 50% or 20 – 30% of the film; the filler comprises 5 – 30% or 15 – 25% of the film. The hydrocolloid is selected from natural gums, biosynthetic gums, natural seaweeds, natural plant extrudates, natural fiber extracts, gelatin, processed starch, cellulosic materials, alginates, pectin and combinations thereof; natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthum gum; sodium alginate or calcium alginate; or a carrageenan. The filler is a food grade bulk filler selected from microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, calcium phosphates and combinations thereof; wood; magnesium or aluminum silicates or combinations thereof; mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate or combinations thereof. The magnolia bark extract is about 1 – 10%, 8% 5% of the film; and comprises magnolol and/or honokiol. The composition further comprises an effective amount of a medicament that is that is an oral cleansing, breath freshening agent selected from pH control agents, inorganic components for tartar/caries control, breath freshening agents, anti-plaque agents, anti-gingivitis agents, saliva stimulating agents, pharmaceutical agents, nutraceutical agents, vitamins, mineral and combinations thereof. Specifically, the medicament is urea; phosphates or fluorides; zinc gluconate; chlorhexidene,

CPC, triclosan or combinations thereof; a food acid selected from citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof. The composition further comprising a softening agent at about 0 – 20% or 2 – 10%; and is selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof. The composition further comprises a coloring agent; a flavoring agent at at 0.1 – 20% or 10 – 15%. The flavoring is selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties and combinations thereof; oils of citrus, peppermint, spearmint, mint, clove, wintergreen and combinations thereof; menthol, eucalyptus, thymol and combinations thereof. The composition further comprises an effective amount of emulsifier; that is selected from lecithin, (c10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof.

Dzija teaches pullulan free edible films comprising maltodextrins, hydrocolloids and fillers (abstract). The films further comprise medicaments and other additives for providing oral care, cleansing and breath freshening (abstract), to include softeners, colorants, flavors and emulsifiers (col.2 line 65-col3 line 5). The maltodextrin is present at about 5 – 60 or 20 – 40%, the hydrocolloid is present at about 10 – 50% or 20 – 30% and the filler is present at about 5 – 30% or 15 – 20% (col.3). hydrocolloids are selected from natural seaweeds, natural seed gums, natural plant extrudates, natural fiber extracts, biosynthetic gums, gelatins, processed starch, cellulose materials, alginates, sodium alginate, calcium alginate, carrageenans, guar gum, locust gum, tara gum, gum Arabic, ghatti hum agar gum, xanthum gum, pectin, and combinations

thereof (col.3 line 14-28). Fillers include microcrystalline cellulose, cellulose polymers, wood, magnesium and calcium carbonate, ground limestone, silicates such as magnesium and aluminum, clay, talc, titanium dioxide, mono, di, and/or tri-calcium phosphates (col.3 line 28-40). Medicaments include oral cleansing, breath freshening agent selected from pH control agents, urea, inorganic components for tartar/caries control, phosphates, fluorides, breath freshening agents, zinc gluconate, anti-plaque agents, anti-gingivitis agents, chlorhexidene, CPC, triclosan, saliva stimulating agents, food acid, citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, and/or tartaric acids, pharmaceutical agents, nutraceutical agents, vitamins, minerals or combinations thereof (col.3 line 50-68). Softening agents are present at about 0 – 20% or 2 – 10% and are selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof (col.4 line 15–25). Flavoring agents are present at about 0.1 – 20% or 10 – 15% and are selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties, oils of citrus, peppermint, spearmint, mint, clove, wintergreen, menthol, eucalyptus, thymol and combinations thereof (col.4 line 33-45). The emulsifiers are selected from lecithin, (C10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof (col.4 line 46-56).

Dzija does not teach the film wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; or wherein the claimed amounts of magnolia bark extract are present. However Dzija does teach the medicaments may be agents for preventing dental caries, anti-plague agents, and/or anti-gingivitis agents. At the time of the

claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolo and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the film of Dzija, since it was a well known agent for preventing dental caries, plague and gingivitis, as evidenced by Nanba and Scherl. In addition, since such medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract in the film of Dzija, with a reasonable expectation for successfully obtaining the effective edible film of Dzija.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 – 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 41 of copending Application No.s 10/604,914; 10/604,920; 10/604,921; 10/604,923; 10/604,927; 10/604,928; and 10/607,574 in view of Nanba and/or Scherl.

The claims of the above applications each recite an edible film similar to that as claimed. They do not teach the film compositions wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; or wherein the claimed amounts of magnolia bark extract are present. However they do teach the medicaments may be agents for preventing dental caries, anti-plague agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolo and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scheri teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scheri, to include magnolia bark extract in the films of the claimed compositions, since it was a well known agent for preventing dental caries, plague and gingivitis, as evidenced by Nanba and Scheri. In addition, since such medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract, with a reasonable expectation for successfully obtaining the compositions of the claims.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
June 11, 2005
AU 1651